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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/403,056 10/13/99 EMBRECHTS

R JAB-1267

EXAMINER

HM22/1220

AUDLEY A CIAMPORCERO
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK NJ 08933-7003

KT SHORE, U PAPER NUMBER

1615

DATE MAILED:

12/20/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s) or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-14 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-14 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 3
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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DETAILED ACTION

The request for the extension of time, amendment and the associate power of attorney filed on 4-19-01 are acknowledged.

Claims included in the prosecution are 1-14.

Claim Rejections - 35 U.S.C. § 102

- 1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 2. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 2 256 139 of record.**

GB discloses emulsions containing terbinafine and two phospholipids (note the abstract, page 4 and examples). The intended use has no significance in the composition claims.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the reference does not teach a surfactant. The examiner points out that the reference teaches a combination of phospholipids and since phospholipids are known surfactants, the reference meets the requirements of instant

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claims. The examiner cites 5,744,155 (col. 3, line 60 et seq.), and 5,925,334 (col. 9, line 28 et seq.) which show that phospholipids are surfactants. With regard to applicant's arguments that the reference fails to disclose or suggest the use of the claimed antifungal and the claimed phospholipid in quantites producing a mutual synergetic effect on the inhibition of the growth of *Malassezia furfur*, the examiner points out that instant claims are composition claims and do not recite any amounts of the combination; furthermore, applicant has not shown that the amounts taught by the reference do not produce a synergistic effect. The rejection is maintained.

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu (5,456,851), Mason (5,536,742) individually or in combination, further in combination with Fost (5,688,496), (5,648,348) and Vanmiddlesworth (5,164,375).

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Liu discloses shampoo formulations containing the various additives and ketonazole as the active ingredient; Liu also discloses that ketonazole is an anti-fungal agent and is useful for the treatment of psoriasis and seborrheic dermatitis (note the abstract, columns 1-4, Examples and claims).

Mason similarly discloses shampoo preparations containing ketonazole, econazole or miconazole for the treatment of seborrhoea. Mason notes the association of this disease with yeast (fungus) (note the abstract, columns 1-2 and claims).

What is lacking in the above references is the inclusion of a phospholipid in the shampoo preparations.

Fost (496) while disclosing skin and hair care compositions including shampoos containing synthetic phospholipids teaches the excellent properties of phospholipids such as foaming, viscosity building, wetting, cleansing, detergency and conditioning which makes them very useful (note the abstract, col.1, line 18 through col. 2, line 25, col. 6, line 54 et seq., columns 15-17, examples 16-18 and claims).

Fost (348) while disclosing various personal care products teaches that the synthetic phospholipids have excellent antifungal activity (note the abstract, columns 6-7, examples and claims).

VanMiddlesworth teaches that a synthetic phospholipid of his invention has antifungal activity (note the abstract).

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The inclusion of a phospholipid in the shampoo compositions of Liu or Mason would have been obvious to one of ordinary skill in the art since the secondary references clearly teach the excellent properties of the phospholipids and also their anti-fungal activity.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Lie, and Mason do not teach phospholipids; the examiner agrees, but points out that the secondary references teach the use of phospholipids. Applicant argues that the phospholipids in Fost 348 have a structure different from the phospholipids in Fost 496 and therefore, there is neither a disclosure nor a suggestion in Fost 348 to include its antifungal/antibacterial phospholipids. This argument is not found to be persuasive since instant claims do not recite that the phospholipid be anti-fungal/antibacterial phospholipid; the references of Fost clearly indicate the advantages of using phospholipids and indeed as recognized by applicant himself, one of the phospholipids taught by Fost has these properties and furthermore, the phospholipid taught by Vanmiddlesworth has these properties. With regard to the synergistic properties argued, the examiner points out that scope of the claims is not commensurate with the synergistic effect observed with a combination of a specific phospholipid and specific antifungal agent.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See

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MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

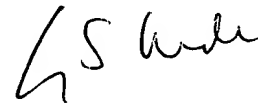
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

June 22, 2001